



UNITED STATES DEPARTMENT OF COMMERCE
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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

09/536,762 03/28/00 YAMANISHI

A 44319-051

EXAMINER

QM12/1012

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ART UNIT

PAPER NUMBER

3736

DATE MAILED:

10/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/536,762

Applicant(s)

YAMANISHI, AKIO

Examiner

Matthew J Kremer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 18 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 18-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected measurement data checking plate, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5.

2. Applicant's election with traverse of Group II in Paper No. 6 is acknowledged. The traversal is on the ground(s) that there would not be a serious burden upon the Examiner to examine Group II since the measurement data checking plate is limited to be used with a bilirubin concentration measuring apparatus. This is not found persuasive because the Applicant states that Group II can be used with a bilirubin concentration measuring apparatus. The Applicant does not state that Group II can be used only with Group I but implies that Group II can be used with other bilirubin concentration measuring devices. Group I is a bilirubin concentration measuring apparatus that functions without the use of Group II. These two devices are separate and distinct. A burden is placed on the Examiner to search for two separate and distinct inventions.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

3. Claims 10 and 17 are objected to because of the following informalities. Claims 10 and 17 recite two limitations as "the logarithmic number". Although use of the limitations are not unclear, Examiner recommends using the limitations "a first logarithmic number" and "a second logarithmic number". Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 10-11 and 17 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Claim 10 recites the limitation "the logarithmic number" in line 8 in which there is insufficient antecedent basis. Claim 17 recites the limitation "the logarithmic number" in line 8 in which there is insufficient antecedent basis.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. Claims 1-2 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 5,830,132 to Robinson. Robinson discloses a method and apparatus for determining one or more concentrations of an analyte in human tissue. (Abstract of Robinson). Bilirubin can be determined (column 1, lines 8-15). In the Abstract, Robinson teaches that the method includes irradiating the tissue at several wavelengths so that there is differential absorption of some of the wavelengths by the tissue as a function of the wavelengths and the known analyte. In column 26, lines 29-49, Robinson discloses an illustration of a finger sampling device which utilizes a single broadband source which is transmitted through a wavelength separating device as seen in Fig. 35. Device 801 includes a wavelength separating device 817 which is an acousto-optic tunable filter that is coupled to base 803 via light pipe 819. The specific wavelength that is emitted from device 817 is transmitted through the finger 11. After transmission through the finger 11, the light at the selected wavelength is then detected by detector rings 831, 833 and 835. It is well known in the art that detectors generate signals that correspond to an intensity of the incident light. The wavelength is changed and another specific wavelength is transmitted through the finger and the process is repeated until all desired wavelengths are transmitted. The signals are processed to calculate the concentration of the analyte (column 23, line 59 to column 24, lines 12). In regard to claim 2, Fig. 36 shows a circular emerging port 817, a first light incident port 831, a second light incident port 833, and a third light incident port 835.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,830,132 to Robinson as applied to claim 1 above, and further in view of U.S. Patent 6,134,458 to Rosenthal. Robinson does not teach a first light incident port in the form of a circle, a light emerging port in the form of a ring outside the first light incident port, and a second light incident port in the form of a ring outside the light emerging port. Fig. 36 shows a circular emerging port 817, a first light incident port 831 in the form of a ring outside 817, a second light incident port 833 in the form of a ring outside 831, and a third light incident port 835 in the form of a ring outside 833. Robinson teaches different embodiments that have different locations for the detectors and emitters. The various detector and emitter locations are functionally equivalent but also allow flexibility as to the location of the sensor on the patient. The various embodiments also allow the operator the choice of the number of emitters and detectors on the apparatus which would be relevant when replacement parts are necessary. Robinson further teaches that the light emerging port can be disposed around the detector which is located in the center as seen in Fig. 32. Rosenthal teaches a light probe for body chemistry measurement in which an illumination ring is concentric with an optical

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detector located in the center. (Abstract and Fig. 2 of Rosenthal). The detector at the center of illumination rings would be functionally equivalent to the detector at the center with light sources disposed around the center as disclosed in Fig. 32 of Robinson et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the detector in the center with illumination rings of Rosenthal for the detector in the center with light sources disposed around the center as disclosed by Robinson since they are functionally equivalent and Robinson implies by the many embodiments that several different emitter/detector locations are possible depending on the number of emitters and detectors that the operator would desire in the apparatus. Robinson teaches that the device can have one detector with several illumination sources or one illumination source with several detectors. It would be obvious from the information of Robinson that a detector in the center and an illumination ring around the center would require either additional illumination rings or detector rings. The detection rings would replace all but one of the illumination rings which would be functionally equivalent to the single detector and multiple illumination rings. The additional detector ring would not heat the patient as an illumination ring and would be more desirable for controlling temperature variations in the tissue. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute a single detector in the center with one illumination ring and multiple detection rings for the single detector and multiple illumination rings of the combination since they are functionally equivalent and an additional detector ring

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would not heat the patient as an illumination ring which would help control temperature variations in the tissue.

10. Claims 4-8 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,830,132 to Robinson as applied to claim 1 above. In regard to claims 4 and 14, Robinson does not teach a first light splitter and a second light splitter. Robinson does teach an embodiment of the invention in which an acousto-optic tunable filter (AOTF) controls the light received by the detector (column 22, line 33 to column 24, lines 27 of Robinson). Robinson teaches that several instrument configurations can be used. (column 22, lines 48-52). It is well known in the art that light splitters are functionally equivalent to the AOTF configuration of Robinson. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute multiple beam splitters for the AOTF configuration of Robinson since they are functionally equivalent and Robinson states that several instrument configurations can be used. In regard to claims 6 and 15, the acousto-optic tunable filter (AOTF) controls the emission of the broadband source. Robinson further teaches that a discrete number of LEDs such as 20 can be used (column 17, lines 61-65) instead of broadband sources. This suggests that multiple LEDs are functionally equivalent to broadband sources. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the multiple LEDs for the broadband source as disclosed by Robinson since they are functionally equivalent and it has generally been held to be within the skill level of the art to substitute elements that

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are functionally equivalent. It is well known in the art that LEDs can be switched in sequence to control the emission of the wavelengths being transmitted into the tissue that would be functionally equivalent to the AOTF controls. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the sequencing of the LEDs for the AOTF controls since they are functionally equivalent and it has generally been held to be within the skill level of the art to substitute elements that are functionally equivalent. In regard to claim 7, Fig. 35 shows channels in finger support surface 805 that act as light guiding members to detector rings 831, 833, and 835. In regard to claim 8 and 16, Robinson teaches that the wavelength region of interest will be 300-1000 nm for bilirubin which covers the entire visible spectrum. (column 27, lines 6-20 of Robinson). Robinson further teaches that there is a significant absorption peak at 454 nm (blue wavelength) for bilirubin. Robinson also teaches that a discrete number of LEDs such as 20 can be used (column 17, lines 61-65). Using 20 LEDs over the span of 300-1000 nm, the result would be center wavelengths every 35 nm. Using 454 nm for the one wavelength as recommended by Robinson and using 35 nm increments, it would be obvious the other wavelengths would be 314, 349, 384, 419, 454, 489, 524, 559, 594, 629, 664, 699, 734, 769, 804, 839, 874, 909, 944, and 979. These wavelengths include: three red wavelengths (664, 699, 734), two blue wavelengths (454, 489), and two green wavelengths (524, 559). In regard to claim 9, it is known in the art that for bilirubin, there is high absorptivity at 450 nm and low absorptivity around 560 nm (U.S. Patent 5,791,345 to Ishihara et al.). Robinson explicitly states that 454 nm should be used

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which has high absorptivity. The combination includes 559 nm which inherently has low absorptivity. In regard to claim 13, other wavelengths are included that have low absorptivity to bilirubin.

11. Claims 10 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,830,132 to Robinson as applied to claims 1 and 13 above, and further in view of U.S. Patent 5,879,294 to Anderson et al. Robinson does not teach calculating 1-4 products by multiplying 1-4 constants by 1-4 electrical signals, a calculation of the logarithmic number of a quotient obtained by division of the second product by the first product, a calculation of a logarithmic number of a quotient obtained by division of the fourth product by the third produce, and calculation of a bilirubin concentration based on the difference. Robinson does teach that quantitative analysis of the processed spectra is performed by a central processing unit in conjunction with a multivariate calibration model and algorithms and the results are in a memory storage unit. (column 24, lines 1-12 of Robinson). It is well known in the art that the steps for processing signals includes using an empirically determined absorption coefficient which is multiplied by the optical absorption value to help determine the analyte concentration. (column 1, lines 36-48 of Anderson). Anderson further discloses that ratios of absorption of measuring and reference wavelengths are used for normalizing which is used to remove some effects of noise. Anderson further teaches that an alternative mathematical model involves determining an analyte concentration by taking the logarithmic value of the measured spectral values. (column 20, line 46 to column

21, line 8 of Anderson). These analyzing techniques as disclosed by Anderson are well known in the art and serve the function to analyze spectra data that is required in Robinson. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus of Robinson to include the analyzing techniques of Anderson since Robinson requires spectral analysis to be performed and Anderson teaches well known techniques for implementing the analysis. The combination of these techniques in which the most appropriate order of analysis can be determined by routine experimentation would, therefore, be prima facie obvious to one having ordinary skill in the art. The product between constants and signals are obvious depending on the calibration data. The ratio between the measurement wavelengths and reference wavelength at one distance and the ratio between the measurement wavelengths and reference wavelengths at the second and third distances are obvious since the normalization will help remove errors due to noise. It is known in the art that the reference wavelength for the ratio is a wavelength in which there is low absorption which includes 560 nm for bilirubin as stated in the previous paragraph. It is obvious to use the transformation using logarithms to determine the analyte measurement from the normalized spectral data. It would be also obvious to use the multivariate analysis to correlate the logarithmic values to a final measurement.

Allowable Subject Matter

12. Claim 11 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

13. The following is a statement of reasons for the indication of allowable subject matter. The prior art does not teach or suggest that a product of a first white electric signal and the first constant is equal to a product of a second white electric signal and the second constant and a product of a third white electric signal and the third constant is equal to a product of a fourth white electric signal and the fourth constant.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 5,983,120 to Groner et al. teaches that absorbing wavelengths of an analyte are normalized by using a reference analyte. U.S. Patent 5,791,345 to Ishihara et al. discloses a blood analyzer that can be used to determine bilirubin that utilizes a blue LED and a green LED. U.S. Patent 5,770,454 to Essenpreis et al. teaches a method and apparatus for analytical determination of a concentration of an analyte including bilirubin. The method includes performing at least two detection measurements. The light is propagated along a light path, and light is detected as it emerges from the biological sample as secondary light through a detection site. At least two detection measurements are performed with at least two different measurement

light paths between the irradiation site and the detection site. U.S. Patent 5,825,488 to Kohl et al. discloses a method and apparatus that can be used in determining bilirubin that includes multiple detection sites. U.S. Patent 5,513,642 to Ostrander discloses a method for determining the content of chemical constituents including bilirubin that has multiple detector strips.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 7:30 a.m. - 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric Winakur can be reached on 703-308-3940. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0758 for regular communications and 703-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Matthew Kremer
Examiner
Art Unit 3736
October 4, 2001



ERIC F. WINAKUR
PRIMARY EXAMINER